UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,483	03/22/2004	Hans-Juergen Kuhr	9134-0252	2791

64108 7590 05/29/2008

BOSE MCKINNEY & EVANS LLP
2700 FIRST INDIANA PLAZA
135 NORTH PENNSYLVANIA STREET
INDIANAPOLIS, IN 46204

EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,483	KUHR ET AL.	
	Examiner	Art Unit	
	AMY T. LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 1-37** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “wherein the needle body comprises a protective portion” in lines 7-8. First it is unclear as to whether the protective portion comprises a sterility cap or elastomer (see paragraph [0034] of the specification) or the plastic body surrounding the lancet needle (see paragraph [0044], lines 16-18 of the specification). Secondly, "comprise" is defined as to include or contain. Therefore, if the protective portion refers to the plastic body (2a), it is unclear as to how the needle body comprises this component. The needle body is disclosed as component (2b). As shown in Figure 2b, the needle body (2b) is disposed within the protective portion (2a) so that the protective portion provides a housing for the needle body. Therefore, it is the examiner's position that the needle body does not comprise, include or contain, the protective portion when the protective portion is the plastic body. Claims 2-11 are dependent on claim 1 and therefore are also rendered indefinite.

Claims 12 and 34 recite wherein the “at least one protective portion of the needle body” in lines 6-7. Therefore, it is also unclear as to whether the protective portion refers to a sterility cap/eslatomer or the plastic body surrounding the lancet needle. As

stated above, if the protective portion refers to the plastic body, it is unclear as to how the needle body comprises the protective portion. Claims 13-20 are dependent on claim 12 and therefore are also rendered indefinite.

Claims 21 and 34 recite wherein the "needle body at least partially surrounds the tip." However, it is unclear as to how the needle body (2b) surrounds the tip when the needle body is attached to the needle and proximal of the tip (see Figure 1b of the specification). Additionally, claim 1 recites wherein the protective portion surrounds the needle tip (lines 10-11). Therefore there is a discrepancy between the claims. Claims 22-33, 36, and 37 are dependent on claims 21 or 35 and therefore are also rendered indefinite.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-13, 15-18, 20-23, 25, 26, and 29-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 5,797,942) in view of Looper (US 2003/0114839 A1).

With regard to **claims 1, 12, 15, 18, 21, and 23**, Schraga discloses a re-useable lancing aid (100) for producing an opening in the skin (see entire document). The lancing aid comprises a removable lancet system (60) having a body and a needle with a needle tip (61) (Figure 2; column 5, lines 15-20). The lancing aid further comprises cap (140) that can be moved relative to the body and therefore overlaps the instantly claimed protective portion (column 5, lines 27-30). In a first position the protective portion partially surrounds the needle tip (column 5, lines 37-44). When the trigger means (13) is activated, the needle body propels forward such that the needle tip extends from the protective portion to pierce a patient (column 5, lines 40-44). In this second position the needle tip emerges from an opening in the lancing aid.

The lancet system (60) is inserted onto the lancet receiving assembly (120) of the lancing aid and enclosed by re-useable end cap (10) to activate the device (column 5, lines 23-30). Lancet system (60) comprises ridges (65) that interact with the lancet receiving assembly (120) and therefore overlap the instantly claimed holding elements (Figure 2).

Although Schraga teaches a re-useable lancing device wherein the distal lancet system is detached and then disposed after use due to contamination (column 5, lines 55-56), Schraga does not specifically disclose a blocking mechanism that prevents the

contaminated lancet from re-use. However, Schraga is open to various modifications and changes (column 9, lines 54-60).

Looper discloses a surgical device wherein a distal end effector is prevented from re-use (see entire document). The end effector includes a biopsy collector, which encompasses lancet devices, and is connected to the shaft of the surgical device through a frangible portion ([0014]; [0017]; [0040]). Once the distal end effector has been utilized and is contaminated, the frangible connection is distorted so that the connection between the surgical device and the end effector is prevented (Figures 2 and 3). This assures that the end effector is used only once for safety ([0043]; [0047]).

Schraga discloses a lancing device with a detachable end effector, the lancet system, that once used is contaminated and must be disposed of for safety issues. It is well known in the art to one of ordinary skill that contamination from a lancet can poses a health hazard if not properly handled. Looper teaches an advantageous blocking method wherein the end effector is prevented from being used more than once so that a contaminated end effector is not re-used. Since Schraga is open to various modifications and Looper teaches an advantageous way to prevent a lancet system from being used more than once, it would have been obvious to one of ordinary skill at the time of the invention for the lancet device of Schraga to comprise the blocking mechanism of Looper so that the lancet system of Schraga has a frangible connection with the lancing aid.

With regard to **claims 2, 4, 5, 25, and 29**, Schraga in view of Looper disclose a lancing aid that is prevented against re-use. Looper teaches that it would have been

obvious for the lancing aid of Schraga to comprise a frangible connection between the lancet system and lancing aid and produce a blocking mechanism. This blocking mechanism prevents the holding element of the lancing system from interacting with the holding element of the lancing aid. Therefore, the ridges (65) on the holding element would be manipulated so that they could no longer interact with the lancet receiving assembly (120 (Figure 2). It further would have been obvious to one of ordinary skill in the art for the lancet system (60) to be prevented from inserting into the lancet receiving assembly (120) so that a user cannot mistakenly attempt to use an unsterile lancet. Therefore, the ridges would be manipulated in such a way that they are prevented from interacting and inserting into the lancet receiving assembly. This would then also prevent the lancet from firing a needle into a patient.

With regard to **claim 3**, as shown in Figure 2, ridges (65) are independent acting holding elements that coincide with independent grooves within the lancet receiving assembly.

With regard to **claim 6**, once the blocking mechanism is activated and the frangible connection is broken, the lancet system and lancing aid no longer interact. Therefore, it is the examiner's position that it also would have been obvious at the time of the invention for the grooves (65) and lancet receiving assembly (120) of Schraga to be able to reinsert but not interact in such a manner to fire a lancet. The connection between these two components would be broken, in view of Looper, allowing the two components to come together but not line up accordingly into a firing position.

With regard to **claims 7-9 and 22**, although Looper teaches the blocking mechanism actuated when the end effector is removed from the surgical device, Looper does not specifically disclose the actuation when the end effector is connected to the device or during the lancing operation. However, it would have been obvious to one of ordinary skill at the time of the invention for the blocking mechanism to be actuated when connected to the device or during the lancing operation. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify when the frangible connection is broken because Applicant has not disclosed that actuating the actuation before, during, or after the lancing operation provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the actuation when the lancet is removed because the connection is still broken to prevent re-use.

With regard to **claim 10**, Schraga further teaches wherein the needle tip returns to the first position, partially surrounded by the protective portion (140) after the lancing procedure (column 5, lines 44-46). The lancet system is then removed from the lancing aid and disposed of when in this configuration (column 9, lines 26-35).

With regard to **claims 11 and 30**, Schraga discloses that the first position is the same as the resting position (column 5, lines 44-46).

With regard to **claim 13, 16, and 20**, the frangible connection taught by Looper produces a connection on the needle body that is broken. Therefore, the shape of the

needle body changes and becomes smaller. Additionally, the break destroys the holding element on the lancet system.

With regard to **claim 17**, ridges (65) on the lancet system overlap the instantly claimed holding element. There ridges comprise part of the shape of the needle body.

With regard to **claim 26**, as shown in Figure 2 of Schraga, lancet (60) comprises a ring that is moveable with respect to the lancet receiving assembly (120). Specifically, the shape of the lancet system is generally in the form of a ring and is moveable since the lancet system is able to move into and out of the lancet receiving assembly (12). When the blocking mechanism is activated by breaking a frangible connection in lancet (60), the movable ring is prevented from interacting with member (120).

With regard to **claims 31 and 32**, since the lancet system of Schraga is able to move between a resting position and a lancing position until engagement means (30) is activated by the user (Figures 5A and 5B), the needle is therefore configured to move between these two positions multiple times after the needle body is inserted into the lancing aid. Furthermore, it is the examiner's position that the needle is also configured to move between the second resting position and the lancing position after the blocking mechanism is actuated. The blocking mechanism of Schraga in view of Looper only prevents a used lancet from being re-inserted into the lancing aid. It does not prevent a lancing needle from firing into a patient. Although Schraga in view of Looper do not specifically teach re-using a needle before the lancet system is removed from the lancing aid, it is the examiner's position that Schraga in view of Looper is capable and configured to.

6. **Claims 12, 14, 21, and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Le Vaughn (US 2005/0015020 A1) in view of Looper (US 2003/0114839 A1).

LeVaughn discloses a lancing device (see entire document) comprising a housing, lancing aid, and a plurality of lancets within a magazine cartridge ([0009]). Each lancet comprises a needle tip and body so that the magazine cartridge overlaps the instantly claimed lancet system ([0107]). The magazine is removable from the lancing aid device ([0014], [0098]). Projection (85) provides a holding element between the lancet system and lancing aid ([Figure 4).

The lancets tips are initially secured within a sleeve (100) in a first position ([0104]; Figure 8). In a second position the lancet tips extend from the sleeve to pierce a patient ([0104]). Therefore, the sleeve clearly overlaps the instantly claimed protective portion.

LeVaughn does not specifically disclose a blocking mechanism that prevents the lancet system from re-use after being removed from the lancing aid. However, LeVaughn is open to various modifications and changes ([0134]).

Looper discloses a surgical device wherein a distal end effector is prevented from re-use (see entire document). The end effector includes a biopsy collector, which encompasses lancet devices, and is connected to the shaft of the surgical device through a frangible portion ([0014]; [0017]; [0040]). Once the distal biopsy collector has been utilized and is contaminated, the frangible connection is distorted so that the connection between the surgical device and the biopsy collector is prevented (Figures 2

and 3). This assures that the biopsy collector is used only once for safety ([0043]; [0047]). Therefore, Looper teaches a blocking method that advantageously prevents re-use of a biopsy/lancet device.

It is well known in the art to one of ordinary skill that contamination from a lancet can poses a health hazard if not properly handled. Once a lancet has been inserted into a patient it is contaminated and should not be re-used. Looper teaches an advantageous blocking method wherein the biopsy collector is prevented from being used more than once so that a contaminated biopsy collector is not re-used. Since LeVaughn is open to various modifications and Looper teaches an advantageous way to prevent a lancet system from being used more than once, it would have been obvious to one of ordinary skill at the time of the invention for the lancet device of LeVaughn to comprise the blocking mechanism of Looper so that the lancet system of LeVaughn has a frangible connection with the lancing aid.

Response to Arguments

7. Applicant's arguments, filed 01/22/2008, with respect to the drawings objection and the 35 U.S.C. 112 rejection have been fully considered and are persuasive. The objection and rejection have been withdrawn.

8. Applicant's arguments filed 01/22/2008 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that actuating the blocking mechanism before, during, or after the lancing operation is not obvious and the Applicant is not required to disclose any particular advantage as to why the lancing operation is performed before, during, or after the lancing operation.

With respect to argument (A), attention is drawn to paragraph [0029] of the instant specification where the Applicant is open to the time at which the blocking mechanism is actuated and does not specifically disclose an advantage for a particular time. Therefore, it is the examiner's position that actuation of the blocking mechanism is obvious at any of the times before, during, or after the lancing operation.

9. Specifically, applicant argues (B) that if blocking mechanism of Schraga in view of Looper were actuated upon insertion of the needle body into the lancing aid the device would be inoperable.

With respect to argument (B), Looper in view of Schraga disclose a frangible connection between the lancet system and the lancet receiving assembly that produces a blocking mechanism. Therefore, it is the examiner's position that the frangible connection is able to break while the lancet system is inserted into the lancet receiving assembly. The device would still be able to operate as intended where a lancet needle is fired into a patient. Once the lancet system is removed from the lancet receiving assembly, the frangible connection then prevents the two from interacting again. The frangible connection as taught by Looper teaches that it is known in the art to prevent re-insertion of a needle into a device to prevent re-use of the needle.

10. Applicant's arguments with respect to all other claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

05/20/2008
/Amy T Lang/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731